



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service

Food and Drug Administration  
Kansas City District  
Southwest Region  
11630 West 80<sup>th</sup> Street  
P.O. Box 15905  
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

July 12, 2002

**CERTIFIED  
RETURN RECEIPT REQUESTED**

WARNING LETTER  
KAN #2002-08

Barbara J. Dunning, CEO & President  
Medicate Home Care Equipment  
205 E. Karsch  
Farmington, MO 63640

Dear Ms. Dunning:

We inspected your medical oxygen transfilling operation located at 312 E. Karsch, Farmington, Missouri during June 12 - 18, 2002. Significant deviations from the Current Good Manufacturing Practice (CGMP) Regulations (Title 21, Code of Federal Regulations, Part 211) were observed. These deviations cause the Compressed Oxygen USP transfilled at this location to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (Act). Significant deviations include, but are not limited to the following:

Failure to calibrate the [REDACTED] Oxygen Analyzer in accordance with standard operating procedures using certified standard cylinders of oxygen and [REDACTED] [21 CFR 211.160(b)(4)].

Failure to follow written production and process control procedures. [21 CFR 211.100(b)]  
For example,

- The temperature of cylinders was not correctly monitored during filling.
- An odor test on cylinders was not performed prior to filling.
- A heat of compression check to verify the cylinders are properly filling was not performed.
- A leak test on cylinders during or after filling was not performed.

Failure to establish and follow adequate procedures for handling and investigating complaints regarding product quality. [21 CFR 211.198]

Failure to establish and operate an effective quality control unit [21 CFR 211.22].

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Failure to establish and implement an effective employee CGMP training program [21 CFR 211.25].

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your firm adheres to all current regulations applicable to your operations.

By copy of this letter, we are advising the Centers for Medicare & Medicaid Services (CMS) that our inspection of your firm revealed significant deviations from the Act. They may elect to defer or discontinue payment for any health care product in violation of state or federal law.

You should know that these serious violations of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizure and/or obtaining a court injunction against further marketing of your medical oxygen. Also, other Federal Agencies are advised of Warning Letters, such as this one, that are issued so they may consider this information when awarding government contracts.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking to correct the problems. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction.

Your reply should be sent to Nadine Nanko Johnson, Compliance Officer, at the above address.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles W. Sedgwick", written over a horizontal line.

Charles W. Sedgwick  
District Director  
Kansas City District

cc: Perry W. Bramhall, Manager